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SENATE BILL 1360
By Henry

HOUSE BILL 1410
By Shepard

AN ACT to amend Tennessee Code Annotated, Title 39 and 53, relative to generic and therapeutic substitution of prescription drugs.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 39 Chapter 17, is amended by deleting Section 421 in its entirety and substituting instead the following language.

§ **39-17-421.** (a) Except as provided in Title 53, Chapter 10, Part 2, it shall be unlawful for any pharmacist, or any pharmacy technician or any pharmacy intern under the supervision of a pharmacist who dispenses prescriptions, drugs, and medicines to substitute any drug or device different from the one ordered, or deviate in any manner from the requirements of an order or prescription without the approval of the prescriber as defined in 63-10-204.

(b) A violation of this section is a Class C misdemeanor.

SECTION 2. Tennessee Code Annotated, Title 53, Chapter 10, is amended by deleting Part 2 in its entirety and by substituting instead Sections 3 through 12 of this act as new Part 2.

SECTION 3. This act shall be known and may be cited as the “Tennessee Affordable Drug Act of 2005.”

SECTION 4. Legislative intent.

The general assembly declares it to be the public policy that in order to lower the cost of prescription drugs to its citizens, pharmacists should be enabled to substitute less costly generic or therapeutically equivalent drugs or drug products for higher priced brand name or trade name drugs or drug products.

SECTION 5. As used in this part in unless the context otherwise requires:

(1) “Brand name” means the registered trademark name of a drug or drug product given by its manufacturer, labeler or distributor;

(2) “Finished dosage form” means that form of a drug which is, or is intended to be, dispensed or administered to a patient and requires no further manufacturing or processing other than packaging, reconstitution or labeling;

(3) “Generic equivalent” means a drug product which has the same established name, active ingredient(s), strength or concentration, dosage form, and route of administration and which is formulated to contain the same amount of active ingredient(s) in the same dosage form and to meet the same compendial or other applicable standards (i.e. strength, quality, purity, and identity), but which may differ in characteristics, such as shape, scoring, configuration, packaging, excipients (including colors, flavors, preservatives), and expiration time;

(4) “Therapeutic equivalent” means a drug product with a different chemical structure than the drug product prescribed but which is of the same pharmacological and/or therapeutic class, and having the same or similar therapeutic effects and adverse reaction profiles when administered to patients in therapeutically equivalent doses;

(5) “Prescriber” means an individual authorized by law to prescribe drugs.

SECTION 6.

Generic substitution authorization – Directions of prescriber.

a) The prescriber shall allow for substitution with a generic equivalent of a brand name drug under all circumstances unless as provided in this subsection.

1) The prescriber documents medical necessity of a brand name drug in the patient’s records due to:

a. Adverse reaction of a patient to a generic equivalent,

b. A generic equivalent is ineffective for the patient,

c. Any other clinically based, prescriber determined need.

For purposes of this subsection, the prescriber's documentation may be satisfied by a copy of FDA Form 3500 submitted in connection with a generic equivalent drug or drug product.

2) A generic equivalent is not available.

b) If the prescriber determines a brand-name prescription is medically necessary for a patient, a written prescription order shall bear, in the prescriber's own handwriting, "Dispense As Written – Brand Name Medically Necessary" or "D.A.W. – Brand Name Medically Necessary."

c) If the prescriber determines a brand-name prescription is medically necessary for a patient and that prescription order is issued verbally, the prescriber shall alert the pharmacist that use of the brand name drug is medically necessary for the patient and describe the reason therefor.

d) Nothing in this section shall be construed to prevent a prescriber from informing a patient of the prescriber's professional opinion as to the capabilities, effectiveness and acceptability of any drug.

SECTION 7.

Therapeutic substitution authorization – Directions of prescriber.

a) If the prescriber determines that substitution with a therapeutic equivalent is appropriate, a written prescription order shall bear, in the prescriber's own handwriting, "Therapeutic Substitution Authorized" or "T.S.A."

b) If the prescriber determines that substitution with a therapeutic equivalent is appropriate, and that prescription order is issued verbally, the prescriber shall alert the pharmacists that substitution with a therapeutic equivalent is permitted.

SECTION 8.

Substitution authorization – Directions of pharmacist.

a) When a pharmacist receives a written or verbal prescription order and the prescriber has not noted medical necessity of the brand name prescribed as required in SECTION 6, the pharmacist shall dispense the least expensive generic equivalent in stock, or a generic equivalent covered under the patient's drug plan.

b) When refilling a prescription order where the prescriber previously noted medical necessity of the brand name prescribed as required in SECTION 6, the pharmacist shall make a reasonable attempt to notify the prescriber if a generic equivalent is available and if authorized by the prescriber the pharmacist shall dispense the least expensive generic equivalent in stock, or a generic equivalent covered under the patient's drug plan.

c) If a pharmacist has reason to belive that the brand name drug or drug product is less expensive to the patient or patient's drug plan than the generic equivalent, the pharmacist shall fill the prescription with the brand name drug or drug product.

d) When a pharmacist receives a written or verbal prescription order and the prescriber has authorized therapeutic substitution for the brand name prescribed as required in SECTION 7, the pharmacist shall dispense the least expensive therapeutic equivalent in stock, or less expensive therapeutic equivalent covered under the patient's drug plan.

e) In the event a pharmacist dispenses a therapeutic equivalent as provided in SECTION 7, the pharmacist shall notify the prescriber or the prescriber's representative of the interchange as soon as practical, but no later than twenty four (24) hours.

SECTION 9.

Responsibility of pharmacist.

A pharmacist who selects a generic equivalent or therapeutic equivalent for substitution pursuant to Sections 6 and 7 has the same responsibility for the selected drug as such pharmacist would in dispensing a prescription for the drug prescribed by its trade or brand name.

SECTION 10.

Contents of label – Record on prescription.

a) The manufacturer, packager, or distributor of any human use legend drug sold, delivered or offered for sale in the state of Tennessee must have printed on the label of the immediate container of the drug the name and address of the manufacturer, packager, or distributor of the finished dosage form of the drug.

b) The pharmacist shall notify the patient of the substitution with a generic equivalent or therapeutic equivalent by noting the substitution on the prescription label. This subsection does not apply to prescriptions dispensed for inpatients of a health or related facility.

SECTION 11.

Every pharmacy in the state shall have posted a sign in a prominent place that is in clear unobstructed view which shall read: “Tennessee law requires pharmacists in some cases to dispense a less expensive generic or therapeutic equivalent for the drug prescribed unless your prescriber directs otherwise. In such event the substitution will be noted on your prescription label. Ask your pharmacist.”

SECTION 12.

In making substitutions as allowed by this part, the pharmacist may use drug products manufactured within the territorial limits of any one of the states of the United States or any other country if such products have been approved by the federal food and drug administration.

SECTION 13. If any provision of this act or the application thereof to any person or circumstance is held invalid, then such invalidity shall not affect other provisions or applications of the act which can be given effect without the invalid provision or application, and to that end the provisions of this act are declared to be severable.

SECTION 14. This act shall take effect upon becoming a law, the public welfare requiring it.